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BEAUTY, LIBERATED

AN INDUSTRY LEADER'S PERSPECTIVE ON THE REGULATION OF NAIL PRODUCTS AND THEIR INGREDIENTS

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WHO IS COTY?

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LEADER AND CHALLENGER IN BEAUTY

Pure play
Beauty company

~$9 billion
net revenue in FY16[1]

77+
brands

180,000+ Retail
and salon customers

Product sold
in **130+** countries

Operations
in **40+** countries

20,000+
employees

2,800 global patents
and counting

10+ manufacturing plants
around the world

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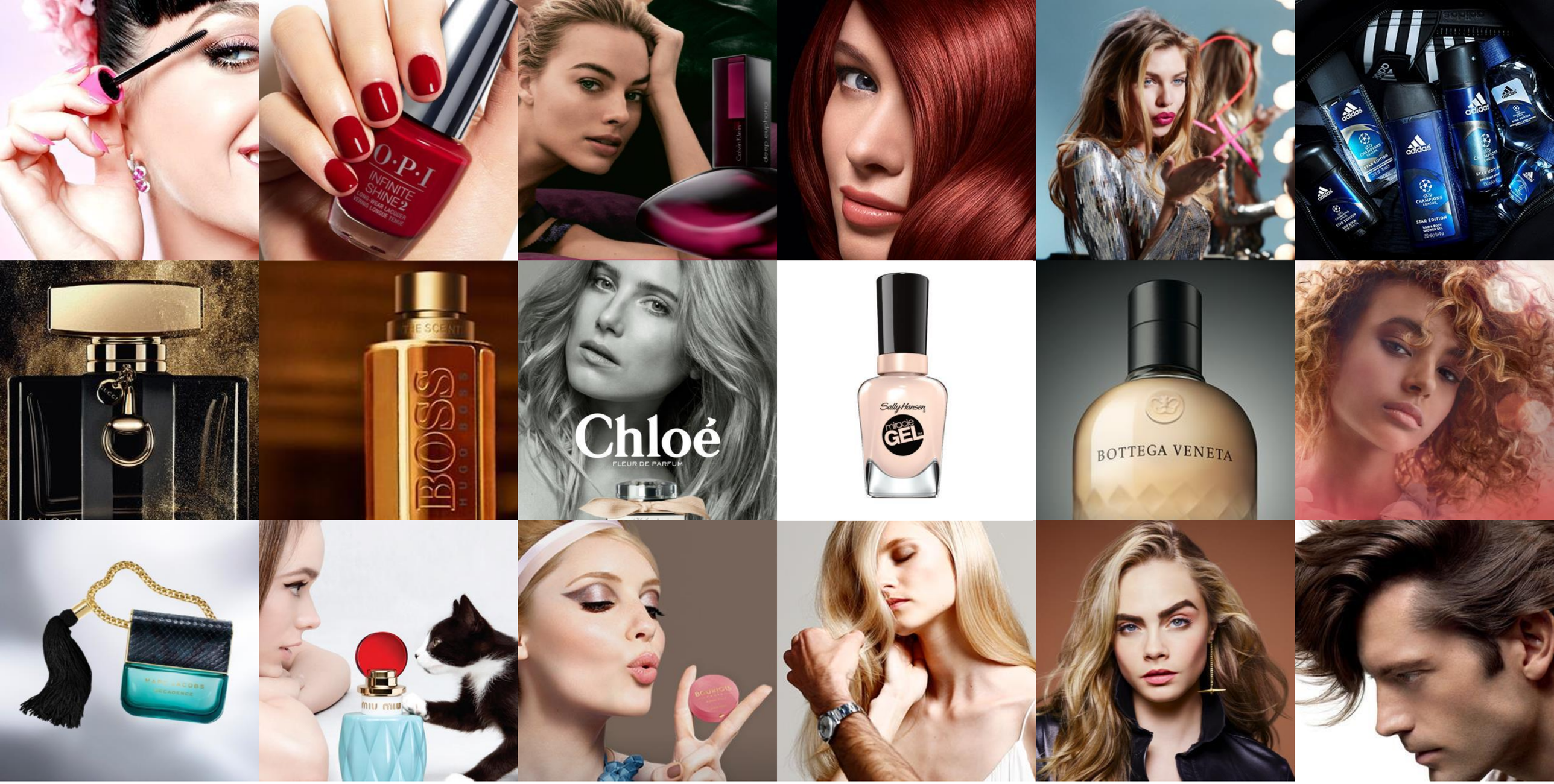
1) Pro Forma for net revenues attributable to the P&G Specialty Beauty Business, annualized net revenues for the Hypermarcas Beauty Business and ghd


O·P·I
INFINITE SHINE 2
deep euphoria
adidas
Chloé
FLEUR DE PARFUM
Sally Hansen
miracle GEL
BOTTEGA VENETA
MARC JACOBS
DECADENCE

OPI PRODUCTS, INC.

- OPI was established in 1981 in North Hollywood California, where it remains to this day.
- OPI manufactures a broad range of products including nail lacquers (polishes), nail treatments, gels, acrylics, nail polish removers, skin care products, sanitation products, tools, and implements.
- OPI sells primarily to salon distributors who, in turn, sell to salons. Salons mostly use OPI products in providing services and, to a lesser extent, resell certain products to consumers.
- OPI is a member of several industry trade associations, including the Nail Manufacturers Council of the Professional Beauty Association and the Personal Care Products Council
- OPI is active in providing knowledge and education to salon professionals.
- OPI was acquired by Coty, Inc. in December 2010.

NAIL PRODUCT 101

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SOLVENT NAIL ENAMELS

- Solvent-based nail enamels are the traditional nail enamels most widely used today.
- Primary components of a solvent nail enamel are:
  - Solvent – Must be able to dissolve polymers and suspend any added pigments until application. Solvents allow for a smooth application, then evaporate to leave a hard polymer coat.
  - Film Former – Added to make Polymers more flexible and chip resistant
  - Plasticizers: Allow polymer chains to slide over each other without breaking,
  - Pigment – Colorants, shimmer agents, glitter

UV-CURED NAIL COLORS

- Instead of starting with a solid polymer, products start with the precursors, solvents are not needed.
  - Monomers
  - Oligomers (short chains)
- System needs a “photoinitiator”
  - Absorbs lights when triggered by a specific UV frequency, provided by a UV or LED lamp.
  - This initiates the chemical reaction which causes the monomers and oligomers to link up into polymers.
  - As with solvent-based nail lacquer, polymer network holds the color and shimmer particles in place.

ACRYLICS – LIQUID/POWDER SYSTEMS

LIQUID:

Comprised of three main components:

- Monomers – Through polymerization (“curing”) molecules link up with other molecules to form long chains. The most common monomer is Ethyl Methacrylate (EMA).
- “Crosslinkers” - Monomers that can link up to more than two chains so that different polymer chains can be connected to each other making the polymer stronger.
- Catalysts – Usually listed as "toluidine" or “tolylamine” compounds which react with the Benzyol Peroxide in the Powder phase to form highly active, short lived molecules called free radicals. These free radicals provide the energy for polymerization.

ACRYLICS – LIQUID/POWDER SYSTEMS

POWDER:

Comprised of three main components:

- Polymer - Polyethyl Methacrylate (PEMA) or Polymethyl Methacrylate (PMMA), a blend of the two, or a copolymer of the two.
- Pigments - Such as Titanium Dioxide or D&C approved pigments. Glitter is provided by polymer flakes, and shimmer is provided by Mica, other reflective mineral particles.
- Initiator- Usually Benzoyl Peroxide. This is the other half of the free radical generation reaction mentioned in the liquid phase.

BONDERS AND PRE-PRIMERS

- Bonders
  - Monomers with the ability to bond both to the nail, and to other acrylics
- Pre-Primers
  - Helps to make the nail surface more alkaline before priming.
  - Increases the effectiveness of the primer or nail lacquer

CHEMICALS IN NAIL PRODUCTS

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CHEMICALS IN NAIL ENAMELS

- A variety of solvents, plasticizers, film formers and colorants are used to create nail products.
- A number of these chemicals have come under scrutiny for possible health concerns.
- Chemicals most often discussed over the last decade in relation to nail products are
  - Dibutyl Phthalate
  - Toluene
  - Formaldehyde
  - Triphenyl Phosphate
  - Variety of colorants

DIBUTYL PHTHALATE (DBP)

- Used in Nail Polish, Topcoats, and Basecoats
- Why was it used:
  - Plasticizer used to soften the hard resins that make the nail polish coat. The smaller plasticizer molecules act as "lubricants" between the polymer chains, so the nail polish coat will be more flexible and less likely to chip.
- Safety Concerns:
  - Shown to have estrogenic effects when used at high doses.
  - **BUT**: For a human to get to the dosage-per-body-weight that was used in toxicological tests, it would be necessary to ingest 5 bottles of nail polish, every day. [1]
- Regulation Against :
  - European Union banned Dibutyl Phthalate in 2005 for nail polish use.
    - EU Scientific Committee on Consumer Safety (SCCs) published a report demonstrating the safety of the ingredient shortly after the ban; however the ban was not lifted.

Coty reformulated out of DBP in 2008

[1] Dibutyl Phthalate – Summary Risk Assessment (2003 w/ 2004 addendum), European Commission Joint Research Centre, Institute for Health and Consumer Protection, European Chemicals Bureau, Italy.

TOLUENE

- Used in Nail Polish, Topcoats, and Basecoats
- Why was it used:
  - Solvent that enables the nail polish to be spread in a smooth coat.
- Safety Concerns:
  - At high exposure levels it can present a cancer and reproductive system risk .
    - Research in salons, supervised by the State of California, showed that the toluene exposure for a nail tech working an 8 hour day was 1/200th of the federally established (OSHA) safe exposure level. For the customer, it's even lower. [3]
- Regulation Against :
  - No set regulations against the use of Toluene in nail, though Consumers have requested that nail products be formulated without the material.

Coty voluntarily ceased the use of Toluene in 2012

[3] McNary J.E., Jackson E.M. (2007). Inhalation Exposure to Formaldehyde and Toluene in the Same Occupational and Consumer Setting, *Inhalation Toxicology* 573-576

FORMALDEHYDE

- Used in Nail Hardeners
- Why it is used:
  - Acts as a crosslinking agent that stiffens fingernail protein
- Safety Concerns:
  - Rare nasopharyngeal cancer is linked to inhaling *large* amounts of formaldehyde gas in *industrial* settings.
  - The OSHA 8 hour workday standard for formaldehyde exposure is 0.75 ppm -- almost 200 times higher than the highest level found in OSHA study (0.0038 ppm).[4]
- Regulation Against :
  - US and Health Canada allow for up to 5% of formaldehyde in nail hardeners.
  - European Commission's Scientific Committee on Consumer Safety (SCCs) assessed the safety of the use of formaldehyde in nail hardeners and concluded that Nail hardeners with a maximum content of about 2.2% free formaldehyde can be used safely to harden or strengthen nails.
    - The SCCS pointed out that formaldehyde occurs naturally, including in some foods, and is formed endogenously in mammals, including humans, as a consequence of oxidative metabolism; and that the aggregate exposure of humans to formaldehyde has been exhaustively reviewed over a long period of time by several expert groups.

Coty only uses Formaldehyde in nail hardeners, no other uses

[4]Winkelman J.G.M., et al. (2002) Kinetics and Chemical Equilibrium of the Hydration of Formaldehyde, *Chemical Engineering Science* 57, 4067.

TRIPHENYL PHOSPHATE (TPP)

- Used in Nail Polish, Topcoats, and Basecoats
- Why is it used:
  - Plasticizer used to soften the hard resins that make the nail polish coat. The smaller plasticizer molecules act as "lubricants" between the polymer chains, so the nail polish coat will be more flexible and less likely to chip.
- Safety Concerns:
  - One or more studies has linked the material to endocrine disruption.
  - World Health Organization (WHO) identified TPP as low toxicity in short-term studies, is not mutagenic, and has not been shown, to cause delayed neuropathy or other neurotoxic changes
  - Triphenyl phosphate does not meet the criteria for persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substance, per the UK Environmental Agency and OECD classifies the material as low hazard potential.
- Regulation Against :
  - US FDA has approved the use of Triphenyl Phosphate as an indirect food additive that may be used in polymers having incidental contact with food.
  - No known Cosmetics regulations against TPP

COLORANTS

- All colorants used in US cosmetics must be approved by FDA.
- Two main classes of colorants use in cosmetics:
  - Colorants that are exempt from certifications
    - FDA maintains a “positive” list of these colorants and a list of permissible end uses
    - Examples include: Iron Oxides, Ultramarines and Titanium Dioxide
  - Colorants that are subject to certification by the FDA.
    - Each batch of colorants manufactured must be reviewed and certified by the FDA to ensure that all applicable specifications are met.
    - Levels of heavy metals – Arsenic, Antimony, Cadmium, Lead and Mercury are carefully tracked.
    - Examples include: FD&C Blue No. 1, D&C Red No. 7, and FD&C Yellow 5.
- Given the global nature of the industry, colorants often also meet purity requirements set forth by the EU Cosmetics Directive and the Japanese Ministry of Health.
- Additionally, most cosmetic companies have strict purity and heavy metal content requirements.

Coty only uses colorants that meet FDA and Coty’s internal requirements.

MANFACTURING & QUALITY CONTROL

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MANUFACTURING & QUALITY CONTROL

- Due to the unique nature of nail lacquer formulas, many cosmetic companies rely on specialized Third-Party Manufacturers to create the bulk.
- Coty, like many cosmetic manufacturers, require certain quality controls from their outside vendors.
  - For Coty, all Third Party Manufacturers are certified as GMP compliant. Many are also identified as FDA OTC manufacturing facilities and are ISO 22716:2007 certified.
  - Quality audits are performed by Coty to validate new manufacturers prior to any business and awarded.
- Following the production of nail products by Third-Party Manufactures, either the finished product or the bulk product is cleared by Coty's internal Quality Assurance.
  - SOPs for quality assurance and product evaluations are followed in all cases.

COTY'S FOCUS ON SAFETY

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CREATION OF SAFETY ASSESSMENTS

- Due to the global nature of our business, Coty ensures compliance of all of their products to all applicable regulations, including the EU Cosmetic Products Regulation.
- The European Cosmetic Products Regulation (EC) 1223/2009 (CPR), which became fully operational from July 2013, is considered the most contemporary regulatory framework concerning state-of-the-art of cosmetic science and product technology.
- The CPR requires that every cosmetic product undergoes a safety assessment that takes into account the intended use of the cosmetic product and the anticipated systemic exposure to individual ingredients in a final formulation and uses an appropriate weight-of-evidence approach, prior to being placed on the market in any of the 28 EU Member States.
  - The cosmetic product safety assessment must be carried out by a person in possession of a diploma or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline, or a course recognized as equivalent by an EU Member State.
- The CPR also requires all EU Member States to monitor compliance with
  - (i) this Regulation via in-market controls of the cosmetic products made available on the market; and
  - (ii) the principles of good manufacturing practices, and to periodically review and assess the functioning of their surveillance activities.

SUBSTANTIATION FOR SAFETY ASSESSMENTS - INTERNAL STUDIES

- These safety tests are additionally used as substantiation for the Safety Assessment.
- Examples of these typical tests are:
  - 1. Repeated Insult Patch Test on a Nail Enamel
    - Studied included 110 test subjects with a total of 9 applications
  - 2. In-Use Safety Evaluation-Dermatologist Evaluations on Nail Polish
    - Studied included 16 test subjects with a total of 8 applications
  - 3. In-Use Safety Evaluation of a Gel Manicure System
    - Studied included 34 test subjects who participated in a 6 week study

SUBSTANTIATION FOR SAFETY ASSESSMENTS - LEVERAGE OF INDEPENDENT STUDIES

- A number of toxicological assessments have been published by independent agencies.
- Examples:
  - Information Network of Departments of Dermatology (IVDK) - Contact Allergy to Urethane Acrylates/Data from Dermato-Allergological Surveillance.
  - California Salon Formaldehyde-Toluene Safety Study
  - Scientific Committee on Consumer Safety (SCCs) Opinion on the safety of the use of formaldehyde in nail hardeners
  - Cosmetic Ingredient Review Board Amended Safety Assessment of Formaldehyde and Methylene Glycol as used in Cosmetics
  - The SCCS Notes of Guidance for the testing of Cosmetic Ingredients and Their Safety Evaluation (9th revision)
  - A.S. Ficheux et al: Probabilistic Assessment of Exposure to Nail Cosmetics in French Consumers.

SALON WORKER SAFETY

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INDUSTRY ACTIONS TO ENSURE SAFETY

- Coty works closely with the Professional Beauty Association (PBA) and the Nail Manufacturers Council (NMC) as a way to communicate information to Salons.
- OSHA-Compliant SDS for OPI Salon products are available through an online portal, many translated into Vietnamese
- At least 18 different guidance documents, many co-authored by OPI Product employees, were provided to PBA and NMC and were then communicated to salon owners.
- Topics included:
  - Ergonomic basics
  - Cleaning and Disinfecting procedures
  - Steps to minimize inhalation and skin exposure
- Guidance documents have been translated in a number of languages including: Korean, Russian, Spanish and Vietnamese.
  - A complete list of currently available documents can be found in the Appendix.

US ENVIRONMENTAL PROTECTION AGENCY GUIDANCE

- Guidance document – Protecting the Health of Nail Salon Workers – released in March 2007
- .Topics included:
  - Best Shop Practices
  - Gloves
  - Masks and Respirators
  - Liquid Methyl Methacrylate Monomer Factsheet.

https://www.epa.gov/saferchoice/protecting-health-nail-salon-workers-0

NAIL INDUSTRY MICROTRENDS

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MICRO TRENDS IN NAIL PRODUCTS

- Consumer-driven manicure is easy to apply, durable, and easy to remove.
- Current solvent-based formula technology provides a manicure that suits the consumer's needs:
    - Easy to apply
    - Endless array of shades
    - Long-wearing
    - Glossy
    - Chip resistant
    - Easy to remove
- Micro trends in alternate technologies do not match the performance of solvent-based technology, and therefore do not meet the consumer needs.
    - An example of one of these trends is water-based nail color.
    - Several popular misconceptions exist concerning water based nail color products when compared to conventional solvent based nail color formulations.

CONCLUSIONS

- The global cosmetic industry is subject to national and international rules and regulations that govern the safety and efficacy of our products.
- While specific requirements may vary from country to country, product safety and regulatory compliance are essential to product marketability in every jurisdiction.
- Many of the ingredient concerns discussed today have proven to be false or unfounded by international bodies.
- Coty, along with other multinational companies, work with the industry to publish guides, in a variety of languages to ensure worker safety.

APPENDIX

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CURRENT SAFETY DOCUMENTS AVAILABLE TO SALONS (1)

- **Information on Particular Product Types/Ingredients**
  - Gel Manicure and Pedicure
    - Description of the Gel technology and application process.
  - Methyl Methacrylate Monomers
    - Document provides information on MMA, a material used widely in nail enhancement products
  - Nail Hardeners: Formaldehyde or Formalin?
    - Contains description and background of nail hardeners, along with information on active ingredients
  - UV Gel Manicures: Proper Removal for Continued Nail Health
    - Description on how best to remove Gel nail products

CURRENT SAFETY DOCUMENTS AVAILABLE TO SALONS (2)

- **Guides and Tips for Workers**
  - Guidelines for Controlling Inhalation Exposure to Nail Products
    - Description of “product overexposure” and tips on how to lower exposure
  - Guidelines for Controlling and Minimizing Skin Exposure to Nail Products
    - Discussion of improving Salon air quality and the use of dust masks by workers
  - Ergonomics Basics for Nail Professionals
    - Improving Body Ergonomics, and preventing Lifting and Motion Injury
  - Nail Salon Workers: Health and Safety, Working Conditions, Compensation and Demographics
    - Broad overview of all topics impacting Salon workers

CURRENT SAFETY DOCUMENTS AVAILABLE TO SALONS (3)

- **Guides on Cleaning and Disinfecting**
  - Pedicure Equipment Cleaning and Disinfecting Procedures
    - Step by step procedures
  - Guideline for Cleaning and Disinfecting Manicuring and Enhancement Equipment
    - Helpful tips on disinfecting methods and chemicals to be used.
  - Investigation of the Potentials for Microbial Contamination in Nail Polish
    - Description of studies commissioned by NMC to illustrate the low risk of microbial contamination

CURRENT SAFETY DOCUMENTS AVAILABLE TO SALONS (4)

- **Educational Documents for Consumers:**
  - Do UV Nail Lamps Emit Unsafety Levels of Ultraviolet Light?
    - Description of the science that illustrates the safety of UV nail lamps
  - Facts about Salon Nail Polish for Consumers
    - Provides helpful FAQ for workers to help educate their consumers on the products being applied.
  - Statement of Professional Beauty Association Nail Manufacturers Council on Safety on Gel Manicures